Agenda

Tuesday, March 17, 2015
Preconference Workshop

:30 a.m. – 9:00 a.m. **Registration and Continental Breakfast**

9:00 a.m. – 12:00 p.m. **Integrating Risk Management Into Complaint Management And CAPA Processes**

The importance of integrating risk management into your processes can't be overstated, and more and more devicemakers are seeing that its effective application helps them better prioritize and focus on their most important concerns – especially with CAPA and complaint management. With complaints on the rise (thanks to social media) and the FDA's high expectations of your CAPA program, embracing the tenets of risk management to improve your processes is a no-brainer. Attend this in-depth session – taught by a risk management expert who deals with complaint management and CAPA every day – and you'll return to your office filled with newly-acquired knowledge and ready to move into a leadership role in this always difficult area.

Attendees will learn:

- Understanding how to review complaints and CAPAs with a risk management mindset to prioritize valuable time and resources
- Creating and writing SOPs that govern and explain how you integrate risk management to manage complaints and CAPAs — the FDA will expect to see these during an inspection
- Managing emerging sources of complaints and applying risk management tools to determine how best to handle them

Larry Kopyta, Vice President, Quality Assurance & Regulatory Affairs, Omnyx, LLC

Tuesday, March 17, 2015
Day 1

12:00 p.m. – 1:00 p.m. **Registration**

1:00 p.m. – 1:15 p.m. **Welcome and Introduction by Co-chair Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding, former FDA Deputy Associate Commissioner for Regulatory Operations**

1:15 p.m. – 2:00 p.m. **Medical Device Single Audit Program Gaining Steam, Canada To Require Audits in 2016**

All signs point to progress with the Medical Device Single Audit Pilot Program, in which a third-party inspector's single audit is considered sufficient to prove compliance in the U.S., Canada, Australia and Brazil. Results to date also suggest that a single audit costs less and takes less time than is required in each separate market. In the meantime, Canada is taking a leadership role, announcing that beginning in 2016, products sold there will require shared audits. And international medical device regulators are trying to entice more companies to participate in the pilot program, promising that they will be spared warning letters except in cases that pose an immediate threat to public health. Plan to attend this session to learn more about this breakthrough pilot and how it could dramatically affect your business.

Attendees will learn:

- How multiple sites will be audited under the program
- Results from results, including comments from both companies and inspectors
- MDSAP has been called QSIT on steroids — is this a true statement and what are the similarities and differences?
- Could EU nation states join the program in 2015?

Kimberly Trautman, Associate Director, International Affairs, Medical Device International Quality Systems Expert, Office of the Center Director, CDRH, FDA (invited)

2:00 p.m. – 3:30 p.m. **FDA Expectations For Risk Management Files And Their Relationship To ISO 14971 Requirements**

Many devicemakers are relying on FMEAs to be the heart of their risk management strategy. But if that's your strategy, you're looking for trouble. For starters, a FMEA is not compliant with ISO 14971, and FDA and international regulators want to see comprehensive risk management that covers and fully documents all the known risks of your product. So, what exactly are the expectations for using risk management files in production and post-production to make smart risk-based decisions? This panel discussion will feature FDA and industry representatives who will explore best practices in using FMEA and ISO 14971 properly — and show you how to avoid the trap of overreacting to every risk that might present itself.

Attendees will learn:

- How FDA views using FMEA, ISO 14971 to remain proactive within your risk management strategy
- What do regulators want to see when they examine risk management files? Is there a sweet spot between too little information and too much?
- Best practices for creating holistic event tracking methods that provide more accurate views of a product's risk profile
- What companies need to do to address the latest in ISO 14971 enforcement — including how devicemakers are struggling with EU compliance

Moderator:
Vinny Sastri, President, WINOVIA

Panelists:
William MacFarland, Director, Division of Manufacturing and Quality, OC, CDRH, FDA
Dr. Joni Foy, Deputy Director, Office of Device Evaluation, CDRH, FDA (invited)
Karl Vahey, Senior Director Global Quality and Compliance, Covidien
Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding, former FDA Deputy Associate Commissioner for Regulatory Operations
Paul Brooks, Senior Vice President, Healthcare Solutions, BSI Group

3:30 p.m. – 3:45 p.m. **Refreshment Break**

3:45 p.m. – 5:00 p.m. **Effective Management of Front And Back Inspection Rooms — Secrets You've Never Heard and Answers To Questions You've Always Wanted To Ask**

As the FDA's field staff continues to grow, that long overdue inspection is more likely than ever to occur. Plus add the FDA's newest push to develop teams of highly qualified investigators with a deep knowledge of your device. Together, you're in for some really tough inspections. Worried? Don't be. This panel will provide you pages of great tips and tricks to designing, staffing and managing your inspectional war rooms. Our experts will also answer those questions that have been nagging at you for years. Don't miss this exciting panel!

Attendees will learn:

- Polite in the front, craziness in the back? It doesn't have to be. Understanding the synergy of the front and back rooms.
- Handling data requests, particularly for electronic records — best practices from inspectional veterans
- Being a SME in your job doesn't make you an inspection SME. Tips for staffing your war rooms with the appropriate people to interact with the FDA

Moderator:
Elaine Messa, President of the Medical Device Practice, NSF Health Sciences, former Director of the Los Angeles District, FDA

Panelists:
Larry Kopyta, Vice President, Quality Assurance & Regulatory Affairs, Omnyx, LLC
William MacFarland, Director, Division of Manufacturing and Quality, OC, CDRH, FDA

5:00 p.m. – 6:30 p.m. **Networking Reception**

Wednesday, March 18, 2015
Day 2

8:30 a.m. – 9:00 a.m. **Continental Breakfast**

9:00 a.m. – 9:15 a.m. **Welcome and Introduction by Co-chair Elaine Messa, President of the Medical Device Practice, NSF Health Sciences former Director of the Los**

Angeles District, FDA

9:15 a.m. – 10:00 a.m. FDA Update On Inspectional Corps Re-Organization — What Does it Mean For Devicemakers?

The FDA unveiled a broad plan that will change the way it inspects devicemakers, handles recalls, issues and reviews enforcement decisions and screens imports, with companies likely to start feeling the impact in 2015. The reorganization will create a distinct inspectorate for just medical devices, eliminating the existing region-based model. In an eight-page document, CDRH outlined the steps it will take to create a new specialized approach to inspections. The plan includes creating specialist investigators who will be extensively trained in specific types of devices. CDRH says it will survey staff to subdivide its inspectorate into subspecialties.

Attendees will learn:

- Why Commissioner Hamberg asked for feedback on how to improve operations
- What's the latest on the specialization and training that investigators are receiving
- Whether 483s and warning letters will be issued more quickly as a result of the streamlining the agency expects to achieve

Steven Silverman, Director, Office of Compliance, CDRH, FDA (invited)

10:00 a.m. – 10:45 a.m. Are Your Toxicology and Biocompatibility Testing Methods Good Enough?

While FDA doesn't mandate the use of specific international standards, they expect devicemakers to use and document toxicology testing methods. When it comes to issues like leachable substances or chemical characterization of materials devicemakers should thoroughly explain the logic behind their testing methods. Some medtech products may fall into "data gaps" within standards and that toxicity data alone won't prove biocompatibility. For biocompatibility, manufacturers need systems testing and possibly other data. The FDA has announced a guidance is in the works on this subject. Add to the basic testing, ensuring the biocompatibility of materials purchased from other manufacturers. A supplier's word should always be backed up by appropriate documents. While most suppliers familiar to the FDA are reliable, there have been cases where foreign purveyors have sold mislabeled materials into the medical device chain. For instance, a case where a material sold as stainless steel, when sent to a metallurgist for testing, turned out to be an unknown metal. Or how raw resin sold as medical grade could degrade during a manufacturing process and render it unsafe.

Attendees will learn:

- How the FDA views ISO 10993 and are there other standards that should be considered in your testing programs
- Tips for providing sufficient documentation to FDA investigators during your next inspection
- Understanding how manufacturing processes could render previously believed safe materials unsafe

- Update on expected guidance

Ronny Brown, Chief, Recall Branch, Division of Risk Management Operations, OC, CDRH, FDA (invited)

10:45 a.m. – 11:00 a.m. Refreshment Break

11:00 a.m. – 12:00 p.m. Classification and Conformity Assessment Routes For Obtaining CE Marketing and European Distribution

In Order to receive a CE marking, you must travel a tortuous path of compliance with myriad regulations, most notably Directive 93/42/EEC … receive a thorough review of your device and its supporting documentation … pass an assessment of your quality systems and technical documentation … and possibly meet "state-specific" registration requirements relating to the language of the device's accompanying information. This session will start you on the right path if you desire European distribution of your devices.

Attendees will learn:

- How to properly review Directive 93/42/EEC and assure you're classifying your device correctly — failure to do so causes nothing but waster time and money
- Best practices for working with Notified Bodies and getting their stamp of approval
- Which states have requirements regarding state-level registration and how to effectively comply
- Why some states require additional language requirements before marketing can begin

Paul Brooks, Vice President, BSI Healthcare Solutions

12:00 p.m. – 1:00 p.m. Lunch

1:00 p.m. – 1:45 p.m. Choosing the Best Device Sample Size for Verification and Validation

If you're like many manufacturers, you understand the essence of the 21 CFR 820.30 requirements: you must run enough test samples of a product so its test results can be successfully applied to full-scale production runs. Also, your sample sizes must be appropriate for the type of testing you're doing and the type of product. And, like many manufacturers, you've probably had trouble for years determining exactly how many units of a product you should test to satisfy the FDA. This presentation will help you select the right statistical methods to make this determination. You'll learn how to get the right sample size to ensure that user requirements are met in the product design. Finally, you'll understand how to put together a statistical methods program for design verification and validation that will satisfy FDA auditors.

Attendees will learn:

- How to examine the discrete or continuous statistical data you collect. With testing involving discrete data, you'll be doing simple pass/fail tests. With continuous data, you'll measure the output of a device, such as cycle times, voltages or pressures
- Determine how many units you must test to provide sufficient confidence

that zero failures in the sample can be interpreted to mean that the product meets the user requirements, including safety factors
- Tips and tricks to look at variability, including variation from unit to unit or from batch to batch, as well as variation in their measurement systems
- Best practices for choosing design verification and validation tests, particularly regarding choice of sample size
- Fully understand the requirements for statistical techniques, including how different techniques can affect the design control process
- And much, much more

Steven Walfish, President, Statistical Outsourcing Services

1:45 p.m. – 2:30 p.m. **Five MDR Traps That Doom Devicemaker Inspections**

FDA inspectors evaluating the adverse event reporting programs at medical device companies are finding a lot of the same problems over and over again. Additionally the FDA commonly finds weak or missing SOPs and procedure manuals. This presentation will provide you benchmarking data and intel to determine how your organization stacks up and are you ready to pass your next FDA inspection.

Attendees will learn:

- How the agency wants you to define "likely" when assessing whether a malfunction is likely to cause or contribute to a death or serious injury if it reoccurred
- How to address FDA inspector's questions during on-site visits when asked about what constitutes a reportable event and what does not
- Best practices for structuring appropriate time frames and deadlines into your adverse event reporting programs
- Why training is key to successful MDR management — how all staff should be trained. That includes anyone who answers the phone. They should know what to do if it's an adverse event call

Patrick Caines, Director, Product Surveillance, GE Healthcare

2:30 p.m. – 2:45 p.m. **Refreshment Break**

2:45 p.m. – 4:15 p.m. **The eMDR Challenge — Test Your Adverse Event Reporting and Implementation Expertise**

Pop quiz: eMDR is an incredibly useful tool to help your company more effectively handle complaints…or eMDR is a technical nightmare that will tax your team and leave you vulnerable to new regulatory review? The answer is up to you. Mishandled, eMDR implementation can take too much of your organization's time and resources. But if you've got a smart plan in place, it can be one of your front line defenses against serious complaint system weaknesses. In this session, you'll learn from leading experts how to get it right, what your options are for implementing, and what the FDA is looking for in your MDR reporting system.

Attendees will learn:

- Requirements for MDRs on events occurring outside the US
- Reporting requirements when no injury has occurred
- Number of reports to file when there are multiple occurrences

- What to do in "User Error" situations

Moderator:
Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding, former FDA Deputy Associate Commissioner for Regulatory Operations

Panelists:
Sharon Kapsch, Chief, MDR Policy Branch, Office of Surveillance and Biometrics, CDRH, FDA
Dr. Isaac Chang, Director, Division of Postmarket Surveillance, Office of Surveillance and Biometrics, CDRH, FDA
Deb Kacera, Regulatory and Industry Strategist, Pilgrim Software

4:15 p.m. – 4:30 p.m. **Closing Comments by Co-chairs Steven Niedelman and Elaine Messa**

Thursday, March 19, 2015
Day 3

8:00 a.m. – 8:30 a.m. **Continental Breakfast** and Registration

8:30 a.m. – 5:30 p.m. **Medical Device Supplier Qualification and Management — Practical Approaches to Cost-Effective Implementation**

The development of extended supply chains raises major issues in risk management. While regulators are looking more closely at device supplier management issues, companies are recognizing the value of risk management in meeting the regulatory requirements.

In addition, risk management can help device manufacturers protect themselves against problems, develop more effective management systems and control costs. You can start to prepare by focusing on these important GHTF guidance documents:

- Control of Suppliers (GHTF/SG3/N17:2008), Control of Products and Services from Suppliers (SG3/N17/2008)
- Risk Management Principles in a QMS (GHTF/SG3/N15R8)
- Corrective Action & Preventive Action in a QMS (GHTF/SG3/N18:2010)

These guidance documents provide the foundation, but lack practical details. This workshop gives you the tools and methods you need for a cost effective implementation.

Attendees will learn:

- The supplier management process and the major steps involved
- The issues of supplier risk management – product risk, business risk, and recalls & liability risk
- How to conduct an on-site supplier audit applying risk management
- How to qualify suppliers that are virtual companies
- Understanding business issues in the supply chain and their risk challenges
- Medical device corrections & removals (recalls)
- How to select and apply supplier metrics and their role in the QMS

- Dealing with FDA record-keeping issues — sponsor vs. supplier

BONUS: Attendees will receive copies of implementation tools, including a process map, sample questionnaire, reevaluation form, audit checklist and more.

Expert Instructors:
John Avellanet, Managing Director & Principal, Cerulean Associates LLC
Dan O'Leary, President, Ombu Enterprises

5:30 p.m. **Training Adjournment**